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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/250,883	02/16/99	RUSSELL J	6131.US.02

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EXAMINER	
MYERS, C	
ART UNIT	**PAPER NUMBER**
1655	7

DATE MAILED: 03/02/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/250,883	Russell et al
Examiner	**Group Art Unit**
Carla Myers	1655

☒ Responsive to communication(s) filed on *Feb 8, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *9-20 and 24* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☒ Claim(s) *9-20 and 24* is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *3*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Applicant's election of group I, claims 9-20 and 24 in Paper No. 6 is acknowledged. In the response of Paper No. 6, Applicants canceled non-elected claims 21-23.

2. The disclosure is objected to because of the following informalities:

On page 51 of the specification, the information concerning the ATCC deposit numbers and date of deposit for the cited clones is incomplete. Furthermore, the location of the ATCC should be amended to recite the new Manassas, Virginia address.

Appropriate correction is required.

3. Claims 9-20 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polynucleotides derived from a BS203 nucleic acid molecule, wherein said polynucleotide has at least 50% identity with SEQ ID NO: 1-14 and fragments thereof. The claims further include nucleic acids which specifically hybridize with "a BS203" nucleic acid sequence and polynucleotides encoding for at least one BS203 epitope. The claims as broadly written include nucleic acids in which sequences are present flanking SEQ ID NO: 1-14. The broadest reasonable interpretation of the claims indicates that the claims are inclusive of BS203 genes and BS203 genomic sequences. However, the specification does not teach any full length BS203 genes or any BS203 genomic sequences. In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which

defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of specifies have been described by their complete structure. In the instant case, only 14 members of the broadly claimed genus have been defined by their structure, i.e. SEQ ID NO: 1-14. No genomic sequences flanking SEQ ID NO: 14 have been defined. It is then determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g. restriction map, chromosomal map position, biological activity of an encoded protein product, etc.). In the instant case, no such identifying characteristics have been provided for any of the polynucleotides. While at the time of filing applicants were in possession of polynucleotides consisting of SEQ ID NO: 1-14, the specification provides no information regarding genomic sequences surrounding the sequences of SEQ ID NO: 1-14. Furthermore, the specification does not identify any additional BS203 nucleic acids other than the consensus sequence of SEQ ID NO: 14. With respect to claims 15 and 24, the specification does not identify any epitopes of BS203. In fact, the

specification does not provide any specific evidence of a BS203 protein and clearly does not define any epitopes of the putative protein. Furthermore, the specification does not exemplify any molecules having 50%, 60%, etc. identity with SEQ ID NO: 1-14. A representative number of species encompassed by the genus of polynucleotides having at least 50% identity with SEQ ID NO: 1-14 are not disclosed in the specification . The limited information provided in the specification is not deemed sufficient to reasonably convey to one of skill in the art that Applicants were in possession of full length BS203 genes, genomic BS203 nucleic acids, BS203 nucleic acids other than that of SEQ ID NO: 14, polynucleotides encoding BS203 epitopes or the broad genus of nucleic acids having at least 50% identity with SEQ ID NO: 1-14 and fragments thereof. Therefore, the written description requirement has not been satisfied for the claims as they are broadly written. Applicants attention is drawn to the Revised Interim Guidelines for Written Description set forth in the Federal Register, December 21, 1999. Vol. 64, No. 244, pages 71427-71440.

4. Claims 9-20 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids consisting of the sequence of SEQ ID NO: 1-14 and sequences fully complementary to SEQ ID NO: 1-14 and nucleic acids encoding the protein of SEQ ID NO: 17-21, recombinant expression systems and host cells containing said nucleic acids and methods for producing polypeptides by expressing said nucleic acids, and nucleic acids consisting of 15-20 or 20-50 contiguous nucleotides of SEQ ID NO: 1-14 (page 29 of the specification) or sequences fully complementary thereto, does not reasonably provide

enablement for polynucleotides derived from BS203 which share at least 50% identity to SEQ ID NO: 1-14 or fragments or complements thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are drawn to polynucleotides derived from a BS203 nucleic acid wherein said polynucleotides have at least 50% identity with SEQ ID NO: 1-14 or fragments thereof. The claims further encompass polynucleotides which encode for at least one BS203 epitope and polynucleotides which specifically hybridize with a BS203 nucleic acid sequence. The specification discloses a single polynucleotide having the sequence of SEQ ID NO: 14 wherein said polynucleotide was constructed by overlapping contiguous clones isolated from breast tissue wherein said clones consist of the sequences of SEQ ID NO: 1-13. The specification has not enabled one of skill in the art to practice the invention as it is broadly claimed for the following reasons. Firstly, it is unclear as to what is considered to be encompassed by BS203 polynucleotides because a clear and concise definition for this phrase is not provided in the specification. While the specification has constructed a single polynucleotide expressed in human breast tissue by determining the consensus sequence of overlapping cDNA clones, the specification has not identified any variants or homologs of this polynucleotide. It is unclear from the specification as to what would be considered to be the functional and/or structural properties of a BS203 polynucleotide. No specific guidance has been provided in the specification as to how to reasonably isolate additional BS203 polynucleotides without undue experimentation. It is well

established that to claim a chemical compound, such as a polynucleotide, the inventor must be able to define the compound so as to distinguish the compound from other materials and the inventor must clearly define the compound in terms of structure and/or function (e.g. nucleic acid sequence, length of nucleic acid, specific functional activity of nucleic acid) so as to provide a permanent and definite idea of the complete and operative invention. Without a clear and fixed definition of the claimed invention, the skilled artisan cannot make and use that invention without undue experimentation. In the instant case, the specification has not clearly defined the structural and functional activities of what is intended to be encompassed by BS203 polynucleotides and proteins. Secondly, the specification has identified only 14 fragments of a BS203 polynucleotide, yet the claims are drawn to nucleic acids having at least 50% identity with SEQ ID NO: 1-14 and fragments of said nucleic acids. Therefore, the claims encompass a phenomenally large genus of nucleic acids, yet the specification teaches only 14 members of this genus. The specification teaches that the disclosed nucleic acids are useful for the specific detection of BS203 or for the diagnosis and detection of breast cancer (see pages 9-10). Yet, the specification has not exemplified any probes or primers having only 50% identity with SEQ ID NO: 1-14 which have been successfully employed to detect BS203 or to detect diseases of the breast. It is highly unpredictable as to whether nucleic acids having such low levels of sequence identity with SEQ ID NO: 1-14 would be useful for specific hybridization to BS203. No guidance is provided in the specification as to what level of sequence identity is required for the claimed nucleic acids to be functional for the hybridization to and detection of BS203 or for the

detection or diagnosis of breast cancer. The claims also include the use of polynucleotides of any minimal length, including 2 or 3 nucleotides, etc. There is no specific guidance provided in the specification for using small fragments of the disclosed polynucleotides as primers or probes to specifically detect breast tissue specific genes. Thirdly, because the claims recite the open claim language "comprising", the claims as written are inclusive of nucleic acids comprising flanking genomic sequences and nucleic acids which consist of the full length BS203 genes. However, the specification does not provide an example of the genomic structure of BS203. There is no disclosure as to what would be the length of the complete gene, of sequences present in the 5' regulatory region of the gene or intronic sequences of the gene. There is also no specific guidance provided in the specification as to how to reasonable isolate the fully length BS203 gene without undue experimentation. Lastly, claims 15 and 24 are directed to polynucleotides which comprise a sequence encoding at least one BS203 epitope. Yet, the specification does not identify any BS203 epitopes and no guidance is provided as to how one of skill in the art would select appropriate fragments of a BS203 protein which function as an epitope. In view of the lack of disclosure in the specification as to portions of the BS203 nucleic acids which would encode for epitopes and in view of the lack of guidance provided in the specification as to how to select nucleic acids which would encode suitable epitopes, undue experimentation would be required for one of skill in the art to successfully identify nucleic acids that could be used to synthesize BS203 epitopes. Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without

'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher,* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". In the instant case, the specification has identified 13 fragments of a BS203 nucleic acid and one consensus BS203 nucleic acid (i.e., SEQ ID NO: 14), yet the scope of the claims encompasses a huge genus of nucleic acids having 50-100% identity with SEQ ID NO 1-14 and fragments of any length of said nucleic acids. Thereby, the scope of the claims do not bear a reasonable correlation to the scope of enablement provided by the specification and undue experimentation would be required to practice the full scope of the claims because this would require randomly analyzing this huge genus of nucleic acids to identify which members may hybridize to BS203 and would be useful for the detection of BS203 or for the detection of breast cancer or which would encode for epitopes of BS203 protein. Such random, trial by error experimentation is considered to be undue. In summary, in view of the high level of unpredictability in the art of identifying new genes and primers and probes and in view of the lack of guidance and information provided in the specification as to what constitutes a BS203 polynucleotide and as to how to distinguish this polynucleotide from other polynucleotides and as to how to isolate other BS203 polynucleotides from other organisms, and because the specification has not exemplified or provided sufficient

guidance as to how to use a representative number of BS203 polynucleotides having 50% identity with SEQ ID NO: 1-14 or fragments thereof or sequences having any level of complementary thereto, undue experimentation would be required to practice the invention as it is broadly claimed.

5. Claims 9-20 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9-20 and 24 are indefinite and vague over the recitation of "BS203". While the specification states that BS203 polynucleotides include genes comprising DNA which has at least about 50% identity with SEQ ID NO: 14, a complete all-inclusive definition is not provided in the specification for "BS203" and the claims do not set forth a specific functional or structural limitation for what is intended to be encompassed by BS203 polynucleotides. It is well established that to claim a chemical compound, such as a polynucleotide, the inventor must be able to define the compound so as to distinguish the compound from other materials. The specification has not clearly defined the BS203 polynucleotide in terms of structure and/or function (e.g. nucleotide sequence, functional activity of any proteins encoded by the polynucleotide, etc) and therefore one cannot determine the meets and bounds of the claimed subject matter.

Claims 9-20 and 24 are indefinite over the recitation of "derived" because this term is not clearly defined in the specification. It is unclear as to what is intended to be meant by a

polynucleotide acid being derived from another nucleic acid. For example, it is unclear as to whether this means that the polynucleotide consists of a fragment of the nucleic acid or whether this is intended to also encompass polynucleotides which are modified versions of the nucleic acid, such that nucleotide additions, substitutions and deletions may be made in the nucleic acid. Clarification of the claims is required. With respect to claim 19, it is further unclear as to how an open reading frame is derived from a BS203 nucleic acid.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-15, 17-20 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Inoue (Proceedings of the National Academy of Sciences (December 1993) 90: 11117-11121).

Inoue (Figure 2) teaches polynucleotides encoding the estrogen-responsive finger (efp) gene wherein the efp polynucleotides share at least 50% identity with a fragment of SEQ ID NO: 14. In particular, nucleotides 64-267 of the efp gene share 59.8% identity with nucleotides 18-221 of instant SEQ ID NO: 1. Because the specification does not define what is encompassed by a "BS203 polynucleotide", BS203 polynucleotides are considered to be any nucleic acids which contains a fragment having at least 50% identity with SEQ ID NO:1 and 14. Accordingly, the polynucleotides of Inoue are considered to be inclusive of "BS203" polynucleotides. The polynucleotides of Inoue are considered to comprise a BS203 epitope because essentially any

fragment of a nucleic acid is expected to encode for a peptide which will elicit some level of an immune response in some organism. With respect to claims 10 and 11, because of the open claim language "has", the claims are inclusive of polynucleotides which contain within them 20-50 or 15-20 nucleotides. The efp polynucleotide comprises 20-50 or 15-20 nucleotides. With respect to claims 19, 20 and 24, Inoue (page 11117) teaches cloning the efp polynucleotides (i.e. λC3) into an expression vector, transfecting host COS-7 cells with the resulting recombinant expression vector and methods for synthesizing efp proteins using said transfected host cells.

7. Claims 9-15, 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al (GenBank Accession No. R77167, N45368 or H15926).

Hillier (GenBank Accession No. N45368) teaches polynucleotides encoding the estrogen-responsive finger (efp) gene wherein the efp polynucleotides share at least 50% identity with a fragment of SEQ ID NO: 14. The polynucleotide of GenBank Accession No. H15926 shares 98% identity with nucleotides 54-249 of instant SEQ ID NO: 14 and the polynucleotide of GenBank Accesion No. R77167 shares 96.2% identity with nucleotides 660-1095 of instant SEQ ID NO: 14. Because the specification does not define what is encompassed by a "BS203 polynucleotide", BS203 polynucleotides are considered to be any nucleic acids which contains a fragment having at least 50% identity with SEQ ID NO: 14. Accordingly, the polynucleotides of Hillier are considered to be inclusive of "BS203" polynucleotides. The polynucleotides of Hillier are also considered to comprise a BS203 epitope because essentially any fragment of a nucleic acid is expected to encode for a peptide which will elicit some level of an immune response in

some organism. With respect to claims 10 and 11, because of the open claim language "has", the claims are inclusive of polynucleotides which contain within them 20-50 or 15-20 nucleotides. The polynucleotide of Hillier each comprise 20-50 or 15-20 nucleotides.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue in view of Linskens et al (U.S. Patent No. 5,744,300).

Inoue (Figure 2) teaches polynucleotides encoding the estrogen-responsive finger (efp) gene wherein the efp polynucleotides share at least 50% identity with a fragment of SEQ ID NO: 14. In particular, nucleotides 64-267 of the efp gene share 59.8% identity with nucleotides 18-221 of instant SEQ ID NO: 1. Because the specification does not define what is encompassed by a "BS203 polynucleotide", BS203 polynucleotides are considered to be any nucleic acids which contains a fragment having at least 50% identity with SEQ ID NO:1 and 14. Accordingly, the polynucleotides of Inoue are considered to be inclusive of "BS203" polynucleotides. The

polynucleotides of Inoue are considered to comprise a BS203 epitope because essentially any fragment of a nucleic acid is expected to encode for a peptide which will elicit some level of an immune response in some organism. Inoue teaches detection of efp nucleic acids by Northern blot hybridization using efp probes in order to identify tissues and cells expressing efp nucleic acids. However, Inoue does not teach attaching the efp polynucleotide to a solid support. Linskens (col. 15-16) teaches that probes comprising EST sequences may be immobilized onto a solid support in order to facilitate hybridization methods and to allow for the detection of cells expressing nucleic acids complementary to said probes. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have immobilized the efp nucleic acids of Inoue onto a solid support as taught by Linskens in order to have provided an alternatively rapid and simple means for detecting expression of efp nucleic acids in tissue samples.

8. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hillier et al (GenBank Accession No. R77167, N45368 or H15926) in view of Linksens.

Hillier (GenBank Accession No. N45368) teaches polynucleotides encoding the estrogen-responsive finger (efp) gene wherein the efp polynucleotides share at least 50% identity with a fragment of SEQ ID NO: 14. The polynucleotide of GenBank Accession No. H15926 shares 98% identity with nucleotides 54-249 of instant SEQ ID NO: 14 and the polynucleotide of GenBank Accession No. R77167 shares 96.2% identity with nucleotides 660-1095 of instant SEQ ID NO: 14. Because the specification does not define what is encompassed by a "BS203

polynucleotide", BS203 polynucleotides are considered to be any nucleic acids which contains a fragment having at least 50% identity with SEQ ID NO: 14. Accordingly, the polynucleotides of Hillier are considered to be inclusive of "BS203" polynucleotides. The polynucleotides of Hillier are also considered to comprise a BS203 epitope because essentially any fragment of a nucleic acid is expected to encode for a peptide which will elicit some level of an immune response in some organism. Hillier does not teach attaching the isolated polynucleotides to a solid support. Linskens (col. 15-16) teaches that probes comprising EST sequences may be immobilized onto a solid support in order to facilitate hybridization methods and to allow for the detection of cells expressing nucleic acids complementary to said probes. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have immobilized the EST polynucleotides of Hillier onto a solid support as taught by Linskens in order to have provided a simple and effective means for detecting expression of the isolated polynucleotides in cell samples.

9. Claims 19, 20 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillier et al (GenBank Accession No. R77167, N45368 or H15926) in view of Inoue.

Hillier (GenBank Accession No. N45368) teaches polynucleotides encoding the estrogen-responsive finger (efp) gene wherein the efp polynucleotides share at least 50% identity with a fragment of SEQ ID NO: 14. The polynucleotide of GenBank Accession No. H15926 shares 98% identity with nucleotides 54-249 of instant SEQ ID NO: 14 and the polynucleotide of GenBank Accession No. R77167 shares 96.2% identity with nucleotides 660-1095 of instant SEQ ID NO: 14. Because the specification does not define what is encompassed by a "BS203

polynucleotide", BS203 polynucleotides are considered to be any nucleic acids which contains a fragment having at least 50% identity with SEQ ID NO: 14. Accordingly, the polynucleotides of Hillier are considered to be inclusive of "BS203" polynucleotides. The polynucleotides of Hillier are also considered to comprise a BS203 epitope because essentially any fragment of a nucleic acid is expected to encode for a peptide which will elicit some level of an immune response in some organism. Hillier does not teach cloning the polynucleotides into expression vectors, transforming host cells with the resulting vectors or expressing polypeptides using the transformed host cells. However, Inoue teaches cloning polynucleotides, particularly polynucleotides encoding efp, into expression vectors, transforming host cells with the resulting recombinant vectors and expressing polypeptides encoded by the polynucleotides using the transformed host cells (see pages 11119-111120). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have cloned the polynucleotides of Hillier into expression vectors, to have transformed host cells with the resulting vectors and to have used the transformed cells to express polypeptides in order to have provided an effective means for synthesizing polypeptides encoded by the isolated polynucleotides which would have allowed for the further characterization of the functional properties of the isolated polynucleotides and the products encoded by the isolated polynucleotides.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor. W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers
February 17, 2000

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER